JUL 1 8 2001

K011206

IV. 510(k) Summary

This summary of safety and effectiveness is being submitted in accordance with the requirements of the Safe Medical Devices Act of 1990 and 21 CFR §807.92.

A. *Date Prepared*

April 17, 2001

B. *General Information*

Manufacturer: Parallax Medical, Inc.
940 Disc Drive
Scotts Valley, CA 95066-4544

Contact: Richard M. Ruedy
Director, Regulatory and Clinical Affairs
(831) 439-0130 phone
(831) 439-1725 fax

C. *Device Information*

Trade Name: Parallax Bone and Vertebral Body Biopsy Needles

Common Name: Bone Biopsy Needle

Device Classification: II

Classification Name: Gastroenterology-Urology Biopsy Instrument

Product Code(s): 78 KNW

Classification Regulation:

21 CFR §876.1075 – Gastroenterology-urology biopsy instrument

D. *Predicate Device Identification*

The subject device is substantially equivalent to the devices listed in Table 2.

Table 2. Predicate Devices

Product (Trade Name)	Manufacturer	510(k) Premarket Notification Number and Date	Intended Use
Mathis Vertebral and Bone Biopsy System	International Medical Systems	K990515 May 13, 1999	This device is intended for use by physicians performing bone marrow biopsy procedures.
Osteo-Site™ Bone Biopsy Needle Sets	Cook Incorporated	Unknown	Used for Vertebral Body biopsy and infusion

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUL 1 8 2001

Mr. Richard M. Ruedy
Director, Regulatory and Clinical Affairs
Parallax Medical, Inc.
940 Disc Drive
Scotts Valley, California 95066

Re: K011206
Trade/Device Name: Parallax Bone and Vertebral Body Biopsy Needles
Regulation Number: 876.1075
Regulatory Class: II
Product Code: KNW
Dated: April 17, 2001
Received: April 19, 2001

Dear Mr. Ruedy:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4659. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsma/dsmamain.html".

Sincerely yours,

for Mark N. Melkerson

Celia M. Witten, Ph.D., M.D.
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

III. Statement of Indications for Use

Indications for Use

510(k) Number (if known): K011206

Device Name: Parallax Bone and Vertebral Body Biopsy Needles

Indications for Use:

Parallax Bone and Vertebral Body Biopsy Needles are intended for use by a physician performing bone or vertebral body biopsy using a coring (cutting) or aspiration technique.

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

for Mark N. Melkerson

(Division Sign-Off)
Division of General, Restorative
and Neurological Devices

510(k) Number K011206

Prescription Use ✓ OR Over-The Counter Use _____

(Per 21 CFR 801.109) (Optional Format 1-2-96)